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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,202	09/11/2003	Orn Almarsson	TPI-350C1	6536

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EXAMINER	
COTTON, ABIGAIL MANDA	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 12/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/660,202	ALMARSSON ET AL.	
	Examiner	Art Unit	
	Abigail M. Cotton	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-37* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2, 9-11 and 37, drawn to a pharmaceutical co-crystal composition comprising an API (active pharmaceutical ingredient) and a co-crystal former, wherein the API and co-crystal former and hydrogen-bonded to each other, classified in class 424, subclass 489, for example.

II. Claims 3-4, drawn to a pharmaceutical co-crystal composition comprising an API, co-crystal former and a third molecule, wherein the API and co-crystal former are both hydrogen bonded to the third molecule, classified in class 424, subclass 489, for example.

III. Claims 5-6, drawn to a pharmaceutical co-crystal composition comprising first and second APIs wherein the APIs are hydrogen bonded to a molecule, classified in class 424, subclass 489, for example.

IV. Claims 7-8, drawn to a pharmaceutical co-crystal composition comprising first and second co-crystal formers, wherein the co-crystal former are both hydrogen bonded to a molecule, classified in class 424, subclass 489, for example.

V. Claims 12-13 and 20-36, drawn to a process for preparing a pharmaceutical co-crystal composition comprising an API and a co-crystal former, as well as processes for modulating the solubility, dose response, dissolution, bioavailability, increasing the stability and decreasing the hygrosopicity of the API for use in a pharmaceutical composition, or

incorporating a difficult to salt API, among other methods, comprising providing the API and co-crystal former, providing crystallization conditions such that the API and co-crystal former are hydrogen bonded to one another and isolating the crystals formed thereby, classified in class 424, subclass 489, for example.

VI. Claims 14-15, drawn to a process for preparing a pharmaceutical co-crystal composition comprising an API, a co-crystal former and a third molecule, by providing the API and co-crystal former, providing crystallization conditions such that the API and co-crystal former are hydrogen bonded to the third molecule, and isolating the crystals formed thereby, classified in class 424, subclass 489, for example.

VII. Claims 16-17, drawn to a process for preparing a pharmaceutical co-crystal composition comprising first and second APIs, by providing the first and second APIs, providing crystallization conditions such that the APIs are hydrogen bonded to a molecule, and isolating the crystals formed thereby, classified in class 424, subclass 489, for example.

VIII. Claims 18-19, drawn to a process for preparing a pharmaceutical co-crystal composition comprising first and second co-crystal formers, by providing the first and second co-crystal formers, providing crystallization conditions such that the co-crystal formers are bonded to a molecule, and isolating the crystals formed thereby, classified in class 424, subclass 489, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-IV are related to inventions V-VIII as product and process of making. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the products as claimed can be made by other materially different process, such as for example by introducing different heating and/or dissolution steps and/or by providing different crystallization solvents.

Because these inventions are distinct for the reasons given above and the search required for Groups I-IV is not required for Groups V-VIII, restriction for examination purposes as indicated is proper. It is noted that while the searches of Groups I-IV and V-VIII may be overlapping, there is no reason to believe that the searches would be co-extensive. In searching Groups V-VIII, the Examiner will be focusing on the patentability of the processes themselves, and not the compositions of Groups I-IV. Conversely, in searching Groups I-IV, the Examiner will be focusing on the patentability of the compositions and not the processes themselves. Accordingly, a search for all groups would pose an undue burden on the Office.

Inventions I-IV are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have a materially different design and mode of operation, because each invention recites a different combination of components (APIs, co-crystal formers, third molecules, etc) that are uniquely hydrogen bonded to each other. For example, the composition of Group I requires an API and a co-crystal former that are hydrogen-bonded to one another, whereas the composition of Group II requires an API, co-crystal former and third molecule where the API and co-crystal former are hydrogen bonded to the third molecule. Thus, the inventions have different designs with regards to the compositional makeup and hydrogen bonding structure, and thus also have a different mode of operation. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper. In particular, it is noted that while the searches may overlap, the searches would not necessarily be co-extensive.

For example, in searching the subject matter of Group I, the Examiner will be focusing on the patentability of co-crystals having an API and a co-crystal former that are hydrogen bonded to one another, and not co-crystals having an API and co-crystal former that are hydrogen-bonded to a third molecule, as in Group II. Conversely, in searching Group II, the Examiner will be focusing on the patentability of co-crystals having an API and co-crystal former that are hydrogen bonded to a third molecule, and not on co-crystals having the API and co-crystal former hydrogen bonded to one another, as in Group I. Accordingly, a search for all groups would pose an undue burden on the Office.

Inventions V-VIII are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have a materially different design and mode of operation, because each invention recites a different combination of components (APIs, co-crystal formers, third molecules, etc) that are uniquely hydrogen bonded to each other. For example, the process of Group V requires an API and a co-crystal former that are hydrogen-bonded to one another, whereas the process of Group VIII requires an API, co-crystal former and third molecule where the API and co-crystal former are hydrogen bonded to the third molecule. Thus, the inventions have different designs with regards

to the compositional makeup and hydrogen bonding structure, and thus also have a different mode of operation. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper. In particular, it is noted that while the searches may overlap, the searches would not necessarily be co-extensive. For example, in searching the subject matter of Group V, the Examiner will be focusing on the patentability of methods of forming co-crystals having an API and a co-crystal former that are hydrogen bonded to one another, and not co-crystals having an API and co-crystal former that are hydrogen-bonded to a third molecule, as in Group VI. Conversely, in searching Group VI, the Examiner will be focusing on the patentability of methods of forming co-crystals having an API and co-crystal former that are hydrogen bonded to a third molecule, and not on co-crystals having the API and co-crystal former hydrogen bonded to one another, as in Group V. Accordingly, a search for all groups would pose an undue burden on the Office.

Inventions I and VI-VIII, Inventions II, V and VII-VIII, Inventions II, V-VI and VIII and Inventions III and V-VII are directed to an unrelated product and process. Product

and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case the products as recited in each of Groups I-IV requires a specific compositional makeup and hydrogen bonding structure such that the products cannot be made by processes that involve components and/or hydrogen bonding configurations other than those specified. For example, the product of Group I requires an API and a co-crystal former that are hydrogen-bonded to one another, and as such cannot be made by the method of Group VI that involves forming a co-crystal of an API, co-crystal former and third molecule where the API and co-crystal former are hydrogen bonded to the third molecule.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper. In particular, it is noted that while the searches may overlap, the searches would not necessarily be co-extensive. For example, in searching the subject matter of Group I, the Examiner will be focusing on the patentability of co-crystals having an API and a co-crystal former that are hydrogen bonded to one another, and not methods of forming co-crystals having an API and co-crystal former that are hydrogen-bonded to a third molecule, as in Group VI. Conversely, in searching Group VI, the Examiner will be focusing on the patentability of methods of forming co-crystals having an API and co-crystal former that are hydrogen bonded to a third molecule, and not on co-crystals having the API and co-crytal former

hydrogen bonded to one another, as in Group I. Accordingly, a search for all groups would pose an undue burden on the Office.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double

patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Due to the complicated nature of the restriction, the restriction requirement is being made via written correspondence in lieu of a telephone interview.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AMC

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER